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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,228	11/12/2003	Maria da Graca Henriques Vicente	Vicente 0210.1	8492

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PATENT DEPARTMENT
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EXAMINER	
CHONG, YONG SOO	
ART UNIT	**PAPER NUMBER**
1617	

MAIL DATE	DELIVERY MODE
11/07/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/712,228	VICENTE ET AL.	
	Examiner	Art Unit	
	YONG S. CHONG	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-13 and 15-23* is/are pending in the application.

4a) Of the above claim(s) *6,10,11,13,17,21 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4-5, 7-9, 12, 15-16, 18-20, 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/12/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/13/2008 has been entered.

Claim(s) 2-3, 14 have been cancelled. Claim(s) 1, 4-13, 15-23 are pending. Claim(s) 6, 10-11, 13, 17, 21-22 have been withdrawn. Claim(s) 1, 4-5, 7-9, 12, 15-16, 18-20, 23 are examined herein.

Applicant's request that claim 13 should be examined on its merits is on the basis that (1) amended claim 13 is consonant with Group 1, and (2) there is no prima facie basis for restricting claim 13 based on the original restriction requirement filed on 3/30/2007.

This is not persuasive because Applicant must realize the sequence of events that lead to this point as it pertains to claim 13. First of all, the scope of original claim 13 was so broad that it was included in both Group I and II since it recited a method of killing a virus in or on a material. Claims in Group I were drawn to a method of inhibiting a viral infection in a patient, with the term "material" being interpreted as the patient. Furthermore, the term "infection" inherently means introduction of a foreign species in a host organism. Later in prosecution, claim 13 was amended to recite a method of killing

HIV in or on a nonliving material. By this, Applicant has changed the subject matter of claim 13 to a non-elected invention. Therefore, newly amended claim 13 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 13 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Applicant's arguments have been fully considered but found not persuasive. The rejections of the last Office Action are maintained for reasons of record and repeated below for Applicant's convenience.

Applicant's request to submit another signed copy of the IDS filed on 11/12/2003 is attached to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The limitation "light having a wavelength, intensity, and duration sufficient to significantly enhance the compound's treatment of viral infection or killing of viruses" renders the claim indefinite as to what type, wavelength,

intensity, and duration of light are sufficient to significantly enhance the compound's treatment of viral infection or killing of viruses. The specification does not define light that is sufficient to significantly enhance the compound's treatment of viral infection or killing of viruses. Therefore, the metes and bounds of patent protection sought for the instant claims have not been defined.

Response to Arguments

Applicant argues that a person of ordinary skill in the art would readily understand the concepts of exposing tissue to light, finding suitable wavelength, intensity, and duration of light that will enhance treatment. Such testing can only be considered routine to those of ordinary skill in the established field of photodynamic therapy.

This is not persuasive because although photodynamic therapy is an established field, one of ordinary skill in the art would not know how to find suitable parameters of light to enhance the treatment of HIV infection in a human. Examiner does not view this as a matter of routine experimentation because treatment of HIV infection by photodynamic therapy is not an established field. Therefore, there would be undue experimentation to determine suitable parameters in photodynamic therapy in the context of treatment of HIV infection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 4-5, 7-9, 12, 15-16, 18-20, 23 are rejected under 35 U.S.C. 103(a) as being obvious over Debnath et al. ("Anti-HIV-1 activity of carborane derivatives of porphyrins," *Med. Chem. Res.*, vol. 9, pp. 267-273, 1999, of record) in view of Vicente et al. (WO 01/85736 A1, of record).

The instant claims are directed to a method of preventing or treating HIV infection by administering to a patient a porphyrin macrocycle comprising one or more carboranyl groups as depicted by compound 33 (Zn(II)-5,15-bis[bis-3,5-(1-methyl-o-carboranyl)methylphenyl]porphyrin tetrapotassium salt).

Debnath teach carborane derivatives of porphyrins, originally designed as boron neutron capture agents, also possess anti-HIV activity (title and abstract). Table 1 lists some examples of boronated porphyrins.

However, Debnath fail to specifically disclose compound 33.

Vicente teach carbon-carbon linked carboranyl-containing porphyrins as neutron capture agents for cancer therapy (title and abstract). A preferred compound is Zn(II)-5,15-bis[bis-3,5-(1-methyl-o-carboranyl)methylphenyl]porphyrin tetrapotassium salt (pg. 25). These porphyrins are used in boron neutron capture therapy for cancer treatment, which includes irradiation by red light (claim 27-29).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to have used the boron neutron capture therapy on a HIV infected patient by administering compound 33.

A person of ordinary skill in the art would have been motivated to use boron neutron capture therapy on a HIV infected patient by administering compound 33 because: (1) both Debnath and Vicente disclose boron neutron capture therapy; (2) both Debnath and Vicente disclose carbon-carbon linked carboranyl-containing porphyrins as neutron capture agents; (3) of the functional art equivalence of the porphyrins disclosed by Debnath and compound 33 disclosed by Vicente; and (4) Debnath teach carborane derivatives of porphyrins possess anti-HIV activity. Therefore, the skilled artisan would have had a reasonable expectation of success in treating HIV infection in a patient by administering Zn(II)-5,15-bis[bis-3,5-(1-methyl-o-carboranyl)methylphenyl]porphyrin tetrapotassium salt or compound 33.

Response to Arguments

Applicant argues that since there is substantial area of uncertainty, that there could have been no reasonable expectation of success. It is the Office's burden to show why the proposed combination would have had a reasonable expectation of success, despite the presence of uncertainty. Applicants take the position that the Office agrees to all thirteen points raised from the 1/10/2008 amendment because no dispute was made.

Specific reference is made to point involving hydrolysis. There would have been no way to predict, with any reasonable degree of certainty, whether antiviral activity would be enhanced, diminished, or even abolished by linking carboranyl groups to a porphyrin macrocycle such that the linkage is resistant to hydrolysis. The mechanism underlying Debnath's observations was unknown. Did hydrolysis of the carboranyl groups enhance antiviral activity?

At the outset, the Office does not agree with all thirteen points raised from the 1/10/2008 amendment. First of all, Debnath and Vicente do not employ different classes of chemical compounds. Both references use boronated porphyrin derivatives for boron neutron capture therapy. Secondly, Debnath does not contemplate the effect that hydrolysis might have on the ester linkages because there is no mention of this anywhere in the reference. Applicant is essentially teaching away from their own claimed invention as it pertains to this issue. Thirdly, the fact that the mechanism of action was understood or not does not take away from the fact that a prima facie case of obviousness was made.

Applicant is reminded that the motivation to use the porphyrin macrocycle (compound 33) as taught by Vicente in the HIV treatment regimen taught by Debnath is because of the functional equivalence between the porphyrin macrocycles. Both are well known to be boron neutron capture agents. Therefore, it is Applicant's burden to show factual evidence that the porphyrin macrocycle (compound 33) as taught by Vicente would not be effective in the HIV treatment regimen taught by Debnath.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong S Chong/
Examiner, Art Unit 1617

YSC